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Gail E. Poulos  
USDA-ARS-OTT  
5601 Sunnyside Avenue, Rm. 4-1183  
Beltsville, Maryland 20705-5131

In Re: Patent Term Extension  
Application for  
U.S. Patent No. 5,135,759

Dear Ms. Poulos :

An interim extension under 35 U.S.C. § 156(d)(5) is enclosed extending the term of U.S. Patent No. 5,135,759 for a period of one year from the original expiration date, i.e., until August 4, 2010. A copy of the Federal Register notice, published on August 4, 2009 at 74 Fed. Reg. 38585, regarding the issuance of the interim extension under 35 U.S.C. § 156(d)(5) is also enclosed. While a courtesy copy of this letter is being sent to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates which are pertinent to any filings before the FDA.

Inquiries regarding this communication should be directed to the undersigned by telephone at (571) 272-7755, or by e-mail at [mary.till@uspto.gov](mailto:mary.till@uspto.gov).



Mary C. Till  
Legal Advisor  
Office of Patent Legal Administration  
Office of the Deputy Commissioner  
for Patent Examination Policy

cc: Office of Regulatory Policy  
Food and Drug Administration  
10903 New Hampshire Ave., Bldg. 51, Rm. 6222  
Silver Spring, MD 20993-0002

RE: MicroSort® Sperm Separation  
Technology  
FDA Docket No.:

Attention: Beverly Friedman

UNITED STATES PATENT AND TRADEMARK OFFICE

In re United States of America as represented

by the Secretary of Agriculture

Request for Patent Term Extension

U.S. Patent No. 5,135,759

: ORDER GRANTING

: INTERIM EXTENSION

On June 8, 2009, patent owner, United States of America, as represented by the Secretary of Agriculture, timely filed an application under 35 U.S.C. § 156(d)(5) for an interim extension of the term of U.S. Patent No. 5,135,759. The patent claims a use of the medical device, the MicroSort® Sperm Separation Technology. The application indicates, and the Food and Drug Administration has confirmed, that a Premarket Approval application (P090004) for the MicroSort® Sperm Separation Technology has been filed by the licensee of the patent owner, Genetics & IVF Institute, and is currently undergoing regulatory review before the Food and Drug Administration for permission to market or use the product commercially.

Review of the application indicates that except for permission to market or use the product commercially, the subject patent would be eligible for an extension of the patent term under 35 U.S.C. § 156, and that the patent should be extended for one year as required by 35 U.S.C. § 156(d)(5)(B). Because it is apparent that the regulatory review period will continue beyond the original expiration date of the patent (August 4, 2009), interim extension of the patent term under 35 U.S.C. § 156(d)(5) is appropriate.

An interim extension under 35 U.S.C. § 156(d)(5) of the term of U.S. Patent No. 5,135,759 is granted for a period of one year from the expiration date of the patent, i.e., until August 4, 2010.

07/28/09  
Date

John J. Doll

John J. Doll  
Acting Under Secretary of Commerce for Intellectual Property and  
Acting Director of the United States Patent and Trademark Office